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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,245

07/22/2003

Shuichi Mizuno

3831.08

9296

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/625,245</p>	<p>Applicant(s) MIZUNO ET AL.</p>	
	<p>Examiner David M. Naff</p>	<p>Art Unit 1657</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: None.
Claim(s) objected to: _____.
Claim(s) rejected: 85-96.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/David M. Naff/
Primary Examiner, Art Unit 1657

Continuation of 3. NOTE: (a) new issues are raised that would require further consideration and/or search by the amendment to claim 91, reciting "107.33 μg of S-GAG" and "105.59 μg of S-GAG" in claims 93 and 95, respectively, reciting in claim 96 "in a collagen solution at a density between 3 and 60 million of cells/mL of the collagen solution" (bridging lines 5 and 6), "7 hours" (line 13), "up to 152%" (line 22), and "non-activated chondrocytes" (lines 24 and bridging lines 27 and 28), and new claim 97. The above recited limitations in claims 91 and 93-96 are new limitations not in the finally rejected claims. An invention as required by new claim 97 is a different invention than previously claimed.

(b) the issue of new matter is raised by the following: the amendment to claim 9. The specification and patent 6,432,713 do not describe a tissue processor as recited by claim 91. In claim 95, "105.59" is not found in the specification. In claim 96, "7 hours" (line 13), "up to 152%" (line 22) (also bridging lines 3 and 4 of claim 97) and "non-activated chondrocytes" (line 24 and bridging lines 27 and 28) are not found in the specification. Reciting "resulting in increase of S-GAG production to 152%", which is an increase from a lower value, in the published specification (paragraph 0228) does not support a range of "up to 152%" with no lower limit. The specification disclosing chondrocytes not subjected to said activation does not support "non-activated chondrocytes" which can be any non-activated chondrocytes. The specification fails to recite or support an invention recited by new claim 97.

Continuation of 11. does NOT place the application in condition for allowance because: the arguments traversing the 102 and 103 rejections are of the type previously responded to, and are unpersuasive for reasons in the previous response. A collagen matrix disclosed by Smith et al will have a pore size of 100-300 μm , or have a pore size sufficiently close to the claimed range that a material difference in cartilage construct will not result. Smith et al seed chondrocytes in the matrix and culture the cells in the matrix. This will require a pore size adequate for efficient infiltration and growth of the chondrocytes. An increase of "up to 152% increase of S-GAG" encompasses any increase less than 152%, which will clearly be inherent in Smith et al. Moreover, there is inadequate evidence that an increase of 152% is not inherent in Smith et al. Arguments based on new limitations in the amended claims are moot since the amendment has not been entered.